SEP 1 2 2001

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: July 13, 2001

Submitter: Bayer Diagnostics

Address: 1884 Miles Avenue
P.O. Box 70
Elkhart, IN 46515
(219) 262-6928

Contact: George M. Tancos R.A.C.
Manager, Regulatory Compliance

Device:
Trade/Proprietary Name: GLUCOMETER ®DEX® TEST SENSOR
Common/Usual Name: Test for glucose in whole blood
Document Control Number: K012205

Classification Name: The GLUCOMETER® DEX® Test Sensor Disc and the GLUCOMETER® DEX family of blood glucose meters are used to test for glucose in blood. In 21 CFR 862.1345, a glucose test system is classified as a Class II medical device.

Predicate Devices: GLUCOMETER® DEX Test Sensor Disc
Manufactured by: Bayer Diagnostics
430 S. Beiger St.
Mishawaka, IN 46544

Device Description: The GLUCOMTER ® DEX® Test Sensor (modified) is for use with the GLUCOMETER® DEX® family of Blood Glucose Meters. The GLUCOMTER DEX Blood Glucose Test System is an over-the-counter (OTC) home test for glucose in blood. The system is used by persons with diabetes and by healthcare professionals in home settings and in healthcare facilities.

Intended Use: The GLUCOMETER® DEX® Blood Glucose Test System is for the self-monitoring of blood glucose as an adjunct to the care of persons with diabetes.

Technological Characteristics:	The GLUCOMETER® DEX® Blood Glucose Test employs and amperometric glucose oxidase method to measure glucose in blood. It is conceptually the same as other blood glucose monitoring products available for blood glucose testing. The Test Sensors are individually sealed in cartridges of ten sensors. Blood glucose results are referenced to plasma glucose. The GLUCOMETER® DEX® Blood Glucose System has a linear response to glucose from 10-600 mg/dL.
Assessment of Performance:	The performance of the GLUCOMETER® DEX® Test Sensor (modified) was studied in both in-house and clinical settings by healthcare professionals and by persons with diabetes. The studies demonstrated that the GLUCOMETER® DEX® Test Sensor (modified) is suitable for its intended use.
Conclusion:	The results of the evaluation of the GLUCOMETER® DEX® Test Sensor (modified) demonstrate satisfactory performance, and are suitable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. George M. Tancos R.A.C.
Manager, Regulatory Compliance
Bayer Group Diagnostics
1884 Miles Avenue
P.O. Box 70
Elkhart, IN 46515-0070

Re: K012205
Trade/Device Name: Glucometer® Dex® Test Sensor
Regulation Number: 21 CFR 862.1345
Regulatory Class: II
Product Code: NBW
Dated: July 13, 2001
Received: July 16, 2001

Dear Mr. Tancos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012205

Device Name: **GLUCOMETER® DEX® TEST SENSOR**

Indications for Use: The GLUCOMETER® DEX® TEST SENSOR is used with the GLUCOMETER® DEX® and GLUCOMETER® DEX®2 Blood Glucose Meters to measure the glucose level in whole blood. The GLUCOMETER® DEX Blood Glucose System is a home use (OTC) device used by persons with diabetes, and by health care professionals in clinical settings for the self-monitoring of blood glucose as an adjunct to the care of persons with diabetes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ **OR** **Over-The-Counter Use** ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012205